### **Decision Memo for Stem Cell Transplantation (CAG-00287R)**

# **Decision Summary**

CMS understands that the language contained in the current National Coverage Determination (NCD) for stem cell transplantation may not clearly indicate the precise course of treatment covered or not covered. Therefore, the Centers for Medicare and Medicaid Services (CMS) has determined the following:

All steps involved in bone marrow or peripheral blood stem cell transplantation and high dose chemotherapy are integral to the course of treatment and covered as a single entity.

Therefore, CMS will change section 110.8.1 A. of Publication 100.3 to read as follows:

Bone marrow and peripheral blood stem cell transplantation is a process which includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high dose chemotherapy or radiotherapy prior to the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. When bone marrow or peripheral blood stem cell transplantation is non-covered, none of the steps are covered.

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## **Decision Memo**

TO: Administrative File: CAG-00287R

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SUBJECT: Stem Cell Transplantation

DATE: November 28, 2005

#### I. Decision

CMS understands that the language contained in the current National Coverage Determination (NCD) for stem cell transplantation may not clearly indicate the precise course of treatment covered or not covered. Therefore, the Centers for Medicare and Medicaid Services (CMS) has determined the following:

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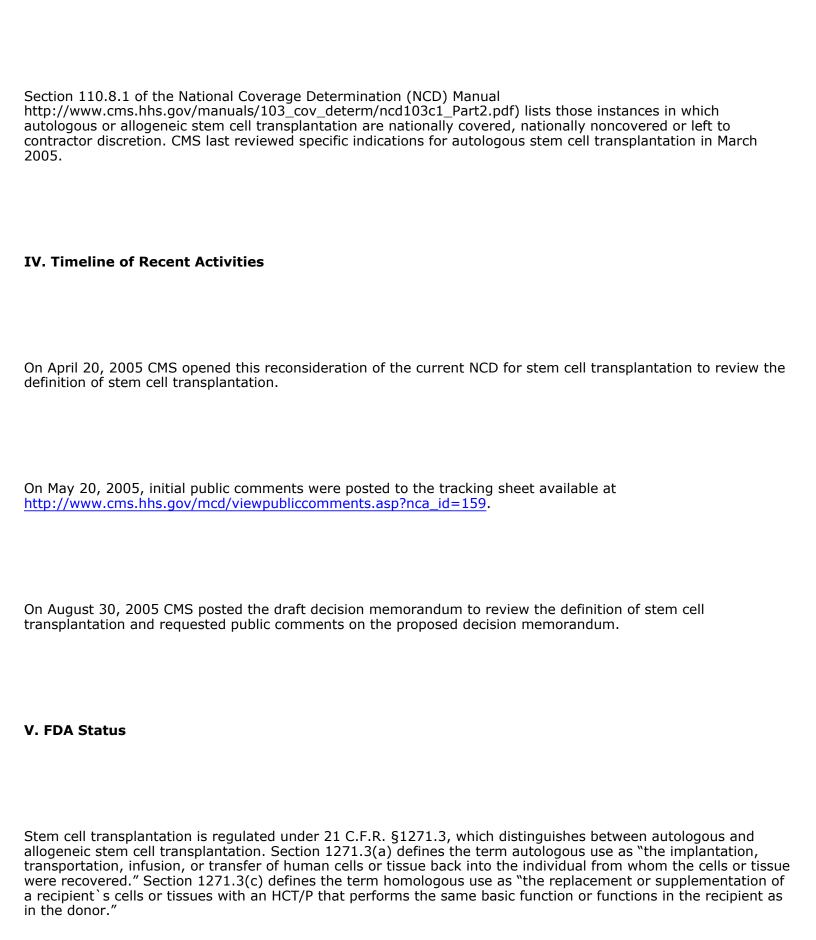
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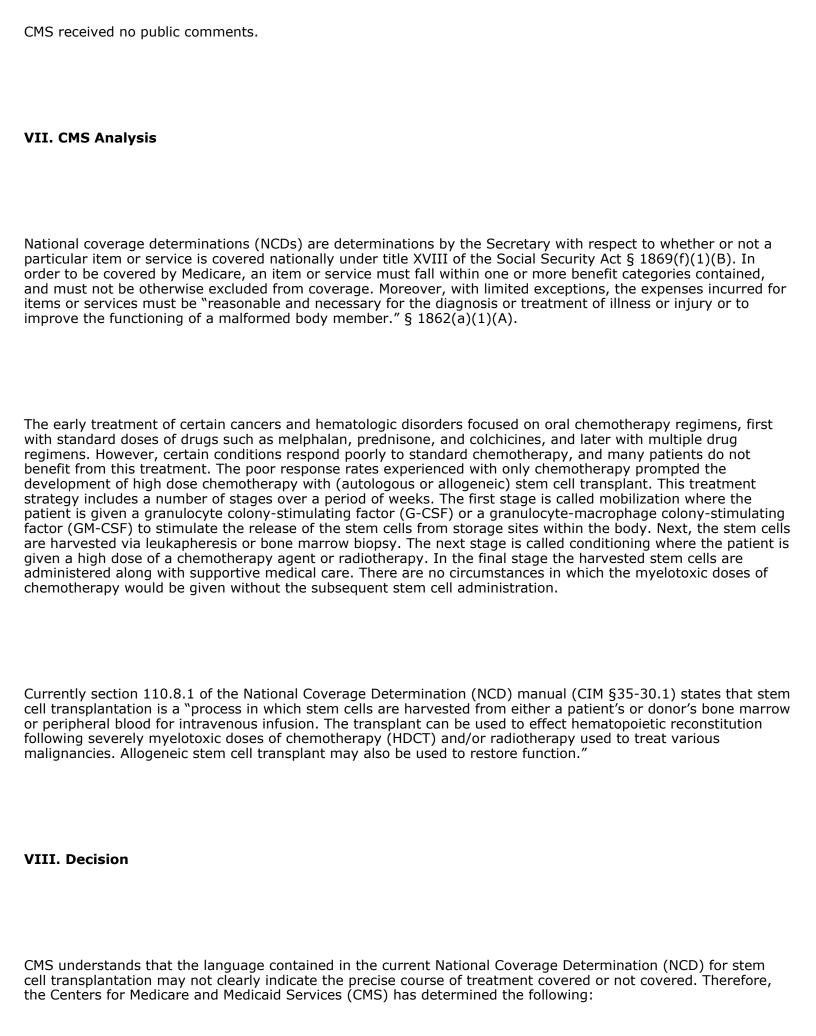
### II. Background

On April 20, 2005, CMS began a reconsideration of the current NCD for stem cell transplantation to review the definition of stem cell transplantation.
Contemporaneously with our last decision on stem cell transplantation in March 2005, CMS became aware of instances in which confusion arose as to the appropriate reimbursement for stem cell transplantation. In some instances, the stem cell transplantation was nationally noncovered but contractor were required by a court to provide coverage for the initial high dose chemotherapy. CMS has elected to internally generate this NCD to address this discrepancy.
In <u>Board of Trustees of University of Arkansas v. Secretary of HHS</u> , 354 F. Supp. 2d 924 (E.D. Ark. 2005), the court determined that the applicable NCD language and manual provisions excluded from coverage autologous stem cell transplant, but supported the coverage of high dose chemotherapy. This finding is troubling because high dose chemotherapy causes significant toxicity that would not be undertaken without a companion remedy offered by the replacement of stem cells. The intent of the stem cell transplant NCD was to cover (or not cover) both high dose chemotherapy and stem cell transplant as a single treatment strategy.
Stem Cell transplantation (Autologous or Allogeneic) is a treatment strategy that includes a number of stages over a period of weeks. The first stage is called mobilization where the patient is given a granulocyte colony-stimulating factor (G-CSF) or a granulocyte-macrophage colony-stimulating factor (GM-CSF) to stimulate the release of the stem cells from storage sites within the body. Next, the stem cells are harvested via leukapheresis or bone marrow biopsy. The next stage is called conditioning where the patient is given a high dose of a chemotherapy agent or radiotherapy. In the final stage the harvested stem cells are administered along with supportive medical care.
III. History of Medicare Coverage
Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage. §1812 (Scope of Part A); §1832; (Scope of Part B); §1861 (s) (Definition of Medical and Other Health Services).

CMS has determined that autologous and allogeneic stem cell transplantation falls within the benefit category of inpatient hospital services under Part A and physicians' services under Part B. See  $\S1812$  (a)(1) (inpatient hospital services);  $\S1832$  (outpatient hospital services incident to a physician's service);  $\S1861$ (s)(2) (incident to physician's services);  $\S1861$ (b) (inpatient hospital services).



Section 1271.3(d)(2) defines human cells, tissues, or cellular or tissue-based products (HCT/P's) as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient. Examples of HCT/P's include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue."	
VI. Evidence	
1. Public Comments	
A. Initial 30-Day Comment Period	
CMS received four initial public comments. Three comments suggest a more comprehensive definition of stem cell transplantation, including providing coverage for the outpatient portions of treatment and reflecting the entire set of services necessary for the procedure. In response, these comments are outside the scope of this reconsideration. A separate NCD request would be needed to address these concerns. One commenter suggested financial incentives for doctors to perform as much of the treatment in the outpatient setting as possible. The commenter notes that currently, CMS offers incentives for inpatient transplant and penalizes programs that can perform transplants in the outpatient setting. Again, this comment is outside the scope of this NCD. A separate NCD request would be needed to address these concerns. One commenter indicates that it would be desirable to separate hematopoietic stem cell acquisition from the transplant itself. For autologous stem cell acquisition this should encompass either bone marrow harvest or peripheral blood stem cell collections. Allogeneic stem cell acquisition should include bone marrow, peripheral blood stem cell and umbilical cord blood as all are standard sources of hematopoietic stem cells. In response, for the purpose of this NCD, stem cell acquisition includes bone marrow and peripheral blood stem cells. All four commenters suggest expanding coverage of stem cell transplants by adding indications including: myelodysplastic syndrome, non-Hodgkin's lymphoma, multiple myeloma, tandem transplant in myeloma, myelofibrosis, relapsed or refractory non-Hodgkins, relapsed or refractory Hodgkins Lymphoma, chemotherapy/medication induced irreversible aplasia, or high risk multiple myeloma. One commenter indicates that efficacy of tandem transplant in myeloma when a complete response is not achieved after the first transplant is proven by the French Myeloma group in NEJM. CMS notes that these comments relate to the expansion of coverage for stem cell transplants, which is not addre	
B. Final 30-Day Comment Period	



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